REMARKS/ARGUMENTS

Reconsideration of the present application is respectfully requested. Claims 1-31 are pending herein. Claims 1, 2, 4-7, 14-18, 20-23 and 30-31 have been amended. Applicants request entry of these amendments and submit that no new matter has been added by way of these amendments.

§ 101 REJECTIONS

Claims 1-31 have been rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Applicants respectfully traverse this rejection and assert that the claimed invention is directed to statutory subject matter.

According to MPEP Section 2106, "[t]he claimed invention as a whole must accomplish a practical application. That is, it must produce a 'useful, concrete and tangible result.' *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of 'real world' value, as opposed to subject matter that represent. Accordingly, a complete disclosure should contain some indication of the practical application for the claimed invention, i.e., why the applicant believes the claimed invention is useful."

The Office Action states that the "result" of the present claims is a determination whether a person has actual genetic findings or providing inferred findings. *See* Office action, Page 3. However, Applicants submit that the "result" of the method of claims 1 and 17, as amended herein, is providing inferred genetic findings to a user so that the inferred genetic findings may be utilized for clinical treatment of a person.

Applicants respectfully submit that providing inferred genetic findings to a user as claimed in independent claims 1 and 17, as amended herein, produces a useful, concrete and tangible result. The "result" of providing inferred genetic findings to a user. The inferred

genetic findings may be utilized by a user to make an informed decision can be made as to whether to pursue a different treatment protocol for the person, incorporate the inferred genetic findings into the care plan for the person and/or order follow-up test results. *See* Specification, paragraphs [0045], [0064], [0065] and [0072]. The useful, concrete and tangible result of providing inferred genetic findings to a user allows clinical decisions for the person to be made with the appropriate knowledge. For example, in paragraph [0065], inferred genetic findings indicating that a person has a 50% chance of a severe reaction to halothane are provided to a user. In response to the information, the surgeon utilizes an alternative protocol. Had the surgeon not been provided with the inferred genetic finding for the person, the surgeon could not have anticipated the 50% chance of severe reaction to halothane and not alerted the protocol used for the patient. Without the inferred genetic finding, the surgeon would have continued to administer halothane to the person and a severe reaction may have occurred. As such, applicants submit that the "result" of providing inferred genetic findings provides a useful, concrete and tangible result allowing inferred genetic results to be incorporated into clinical care of the person.

Furthermore, according to MPEP 2106, "[t]he applicant is in the best position to explain why an invention is believed useful. Office personnel should therefore focus their efforts on pointing out statements made in the specification that identify all practical applications for the invention. Office personnel should rely on such statements throughout the examination when assessing the invention for compliance with all statutory criteria. An applicant may assert more than one practical application, but only one is necessary to satisfy the utility requirement. Office personnel should review the entire disclosure to determine the features necessary to accomplish at least one asserted practical application." Applicants respectfully submit that at least one

practical application of the invention as claimed as been provided and request withdrawal of the § 101 rejection of claims 1-31.

Claims 1-31 also have been rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. Applicants respectfully traverse this rejection and assert that the claimed invention has patentable utility. Claims 1-31 are directed to a new and useful process (method) for providing inferred genetic findings to a user.

According to MPEP Section 2107.01 "[p]ractical utility is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)." Applicant submits that the method for providing inferred genetic findings to a user has an immediate benefit to the public by allowing a clinician to utilize the inferred genetic findings for medical treatment. Applicants respectfully submit that providing inferred genetic findings to a user as claimed in independent claims 1 and 17, as amended herein, provides an immediate benefit for the public. The inferred genetic findings allow a user to make informed clinical treatment decisions for persons using additional knowledge. The person receives a benefit and more appropriate clinical care. *See* Specification, paragraphs [0045], [0064], [0065] and [0072].

Furthermore, according to MPEP Section 2107.01, "[p]ractical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason." Applicants respectfully submit that the invention as claimed is "useful" as described above and request withdrawal of the § 101 rejection of claims 1-31.

§ 112 Rejections

Claims 1-31 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particular point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the office action states that claims 1-7, 9, 11, 13, 15-19, 21-23, 25, 27 and 29-31 recite the limitation "genetic findings." and that neither the claims nor the specification define the limitations. Applicants respectfully state that the specification describes genetic findings in paragraph [0034] as "including genetic test results for any mutations of a particular gene, such as deletions, additions, insertions, inversions, duplications and complex rearrangements and any other type of mutations. Genetic findings may also include DNA sequence information, analysis of polymorphic markers and pheontypic observations." As such, Applicants request withdrawal of the § 112 rejection of claims 1-7, 9, 11, 13, 15-19, 21-23, 25, 27 and 29-31.

The Office action states that claims 1, 17 and 19 recite "actual" genetic findings and it is not clear as to the meaning of such. Applicants submit that "actual genetic findings" represents the fact of the presence of any genetic information for a patient indicating the person has, for example, a mutated (compared to normal) allele, gene, etc. and such is supported by the specification. *See* paragraphs [0033], [0034] [0065] and [0066].

The Office action states that claims 1, 6, 9, 11, 13, 16, 17, 22, 25, 27, 29 and 31 recite "inferred genetic findings" and the limitation is not clear. Applicants submit that the criteria for inferring genetic findings is well described in the specification. *See* Specification, paragraphs [0036] through [0041]. As such, Applicants submit that the limitation is clear and request withdrawal of the § 112 rejection of these claims.

The Office action states that claims 6 and 22 are not clear for reciting "an inferred genetic finding." The Office action states that the relationship between the preamble and the method steps is unclear in claims 1 and 17. The Office action states that there is insufficient antecedent basis for the step limitation in claim 2. The Office action states there is insufficient antecedent basis for "the electronic medical record" in claims 2 and 18. Applicants submit that these claims have been appropriately amended and request withdrawal of the § 112 rejection of these claims.

The Office action states that claim 3 recites a decision support rule and is indefinite. Applicants submit that decision support rules are described in paragraph [0030] of the specification. As such, Applicants request withdrawal of the § 112 rejection of this claim.

The office action states that there is insufficient antecedent basis for the limitation "the traversal pattern" in claims 4, 15, 20 and 30. The office action states that it is not clear what limitation is intended for "the genetic findings" in claims 4-7, 15-16, 20-23 and 30-31. The Office action states that there is insufficient antecedent basis for the limitation "the inferred results" of claim 14. The Office action states that there is insufficient antecedent basis for the limitation "the genetic marker information" of claims 16 and 31. Applicants submit that these claims have been appropriately amended and request withdrawal of the § 112 rejection of these claims.

§ 102 Rejections

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . .

claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP § 2131.

Claims 1-31 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No 2002/0046054 to Morand, et al. As Morand fails to describe, either expressly or inherently, each and every element as set forth in the rejected claims, Applicant respectfully traverses this rejection, as hereinafter set forth.

Independent claim 1, as amended herein, recites a method in a healthcare information technology system for providing inferred genetic findings for a person. The method comprises receiving a request for genetic findings for a person. In response to the request, it is determined if the person has actual genetic findings and if the person does not have actual genetic findings, automatically inferred genetic findings for the person are provided to a user.

Independent claim 17, as amended herein, recites a method in a computer system for providing inferred genetic findings for a person. The method comprises receiving a request for actual genetic findings for one or more genes for a person and determining if the person has actual genetic findings. If the person does not have actual genetic findings, inferred genetic findings for the person are provided to a user.

By way of contrast, Morand is directed to a method for identifying and recruiting donors as candidates for clinical trials. The system of Morand allows an end-user to provide desired subject characteristics to identify individuals. *See* paragraph [0062]. Utilizing the specific characteristics, a query may be done of the clinical trials database for subjects with the desired characteristics. Thus, for example, the database may be searched for specific pharmacogenomic characteristics related to a cytochrome P450. However, Morand does not first determine whether a person has actual genetic findings (e.g., actual genetic test results for a

normal or mutated allele or gene). Morand does not teach providing inferred genetic find gins for the person to a user if the person does not have actual genetic findings. Rather, only one query is performed in Morand for characteristics specified by an end-user. Morand does not teach determining whether a person has actual genetic findings, and if the person does not have actual genetic findings providing inferred genetic findings for the person.

As such, it is respectfully submitted that Morand fails to anticipate independent claims 1 and 17, as amended herein. Accordingly, withdrawal of the 35 U.S.C. § 102(b) rejection of these claims is respectfully requested. As claims 2-16 and 18-31 depend directly or indirectly from claims 1 and 17, withdrawal of the § 102(b) rejection of these claims is requested as well.

Claims 1-11, 14 and 17-27 have been rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent Application Publication No 2003/013727 to Girn. As Girn fails to describe, either expressly or inherently, each and every element as set forth in the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Girn is directed to a process by which an individual may generate family history information to determine whether an individual is a candidate for genetic testing. An individual is prompted to enter family history information and receives a computer-generated evaluation of the information. However, Girn does not first determine whether a person has actual genetic findings (e.g., actual genetic test results for a normal or mutated allele or gene) and if the person does not have actual genetic findings provide inferred genetic findings for the person to a user. Rather, once family history data is entered, a genetic analysis on the entered family history may be performed. *See* paragraph [0081]. Girn does not first determine whether a person has actual

genetic findings and if the person does not have actual genetic findings provide inferred genetic findings for the person to a user.

As such, it is respectfully submitted that Girn fails to anticipate independent claims 1 and 17, as amended herein. Accordingly, withdrawal of the 35 U.S.C. §102(a) rejection of these claims is respectfully requested. As claims 2-11, 14 and 18-27 depend directly or indirectly from claims 1 and 17, withdrawal of the § 102(b) rejection of these claims is requested as well.

§ 103 Rejection

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP §2143 through §2143.03. In order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in

light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)." *Id. See also* MPEP § 706.02(j) and § 2142.

Claims 12-13, 15-16 and 28-31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Girn in further view of U.S. Patent Publication No. 2003/0108938 to Pickar. As neither Girn nor Pickar, alone or in combination, teach or suggest all of the claimed features of independent claims 1 and 17, as amended herein, Applicants traverse the rejection.

As discussed above, Girn fails to teach or suggest all of the claimed features of the rejected claims. Likewise, Pickar also fails to teach or suggest all of the claimed features of independent claims 1 and 17. Pickar teaches computer systems and method for linking biological information to the conduct and success of the clinical trial process for therapeutic agents. Pickar does not first determine whether a person has actual genetic findings (e.g., actual genetic test results for a normal or mutated allele or gene) and if the person does not have actual genetic findings provide inferred genetic findings for the person to a user. Furthermore, the combination of Girn and Pickar fails to teach or suggest determining whether a person has actual genetic findings and if the person does have actual genetic findings providing inferred genetic findings for the person to a user.

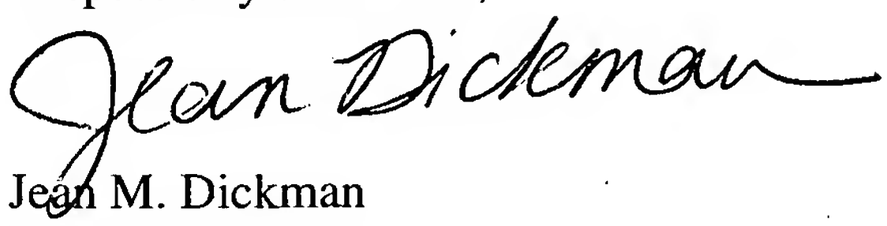
As such, it is respectfully submitted that Girn in view of Pickar fails to teach or suggest all of the claim limitations of independent claims 1 and 17, as amended herein. As claims 12-13, 15-16 and 28-31 depend directly or indirectly from claims 1 and 17, withdrawal of the § 103(a) rejection of these claims is requested.

CONCLUSION

For the reasons stated above, Applicants request that a timely Notice of Allowance be issued in this case. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a

subsequent action. The Commissioner is herby authorized to charge any additional amount required (or to credit overpayment) to Deposit Account No. 19-2112.

Respectfully submitted,



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